

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year) 28.10.2004

Applicant's or agent's file reference
RLL-273WO

IMPORTANT NOTIFICATION

International application No.
PCT/IB 03/02817

International filing date (day/month/year)
16.07.2003

Priority date (day/month/year)
16.07.2002

Applicant
RANBAXY LABORATORIES LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)



Applicant's or agent's file reference RLL-273WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/IB 03/02817	International filing date (day/month/year) 16.07.2003	Priority date (day/month/year) 16.07.2002
International Patent Classification (IPC) or both national classification and IPC A61K31/43		
Applicant RANBAXY LABORATORIES LIMITED et al.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

- This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 13.02.2004	Date of completion of this report 28.10.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Beeck, M Telephone No. +49 89 2399-8473 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/IB 03/02817**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-10 as originally filed

Claims, Numbers

1-76 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/B 03/02817**

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	12, 17-19, 22,23,28,30,31,37-39,49,52,55,56,63,65,66,68,73-75
	No: Claims	1- 11,13- 16,20, 21,24- 27,29,32-36,40-48,50,51,53,54,57-62,64,67,69-72,76
Inventive step (IS)	Yes: Claims	12,17-19,22,23,30,31,37-39,52,55,56,65,66,68,73-75
	No: Claims	1- 11,13- 16,20, 21,24-29,32-36,40-49,50,51,53,54,57-64,67,69-72,76
Industrial applicability (IA)	Yes: Claims	1-76
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB 03/02817

D1: WO 98 35672 A (SMITHKLINE BEECHAM) 20 August 1998 (1998-08-20)
D2: WO 92 19227 A (SMITHKLINE BEECHAM) 12 November 1992 (1992-11-12)

- 1) Document D1 already describes a water dispersable tablet formulation comprising amoxicillin as the β -lactam antibiotic, clavulanate as the β -lactamase inhibitor and a disintegrating agent which is used intragranularly and extragranularly (see page 5, line 24, to page 6, line 35, and page 12, lines 20 to 26, the examples and the claims).

In addition, also document D2 discloses such compositions with or without clavulanate (see the examples in particular).

Therefore the subject-matter of claims 1 to 11, 13 to 16, 20, 21, 24 to 27, 29, 32 to 36, 40 to 48, 50, 51, 53, 54, 57 to 62, 64, 67, 69 to 72 and 76 is not novel (Article 33 (2) PCT).

- 2) The subject-matter of claims 28, 49 and 63 merely consists in an optimization of the contents of the filler.

However, the routine experimentation to optimize the required amounts of ingredients of known compositions for a known use falls within the normal capacity of the average skilled person so that the subject-matter of these claims does not involve an inventive step (Article 33 (3) PCT).

- 3) The remainder of the claims is not obvious in view of the documents cited in the Search Report.

Therefore the subject-matter of these claims involves an inventive step.